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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/315,298	05/20/1999	CHING-LEOU TENG	ISIS-3510	6350

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EXAMINER

EPPS, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 02/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/315,298

Applicant(s)

TENG ET AL.

Examiner

Janet L Epps

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--Th MAILING DATE of this communication appears on the cover sheet with the corresponding address--

THE REPLY FILED 01 February 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:  
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: Claims 1-7, 10, 12-13, 15, 17-20, and 46, 48-64, 80 and 83 remain rejected for the reasons of record.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: see attached note

Continuation of 2. NOTE: Applicant's amendments filed 2-1-02 ("E") and 1-22-02 ("F") will not be entered for the reasons above. Additionally, Applicant's amendment filed 1-22-02 failes to comply with 37 CFR 1.121. In particular Applicants present claims 84-86 as new claims when these claims are actually amended claims 89-91.

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Priority*

2. As stated in the prior office Action, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971). In the instant case, Applicant's claim of priority to Application 09/108,673 as a continuation is improper; the claim to priority is more appropriately a CIP instead of a continuation. The specification of 09/108,673 does not fully support the claimed subject matter of the instant application (MPEP § 201.07).

3. Applicant's arguments filed 2-01-02 have been fully considered, however they are not persuasive. Applicants traversed the Examiner's assessment of priority on the grounds that denying Applicant's priority bases upon the parent application discloses that the compositions are useful for "alimentary delivery" and not "non-parental administration," is improper. However, contrary to Applicant's assertions, the specification and claims of the parent applications do not provide sufficient support for compositions according to the present invention comprising an oligonucleotide, in an

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emulsion, and a penetration enhancer. Therefore, as stated in the prior office action, the instant application contains subject matter that would constitute new matter if inserted in the original application of both 09/108,673 and its parent application 08/886,829.

Therefore, due to the inconsistency regarding the disclosure of the instant application and that of the earlier filed applications of 09/108,673 and 08/886,829 Applicants are not entitled to the earlier filing date of application 08/886,829, filed July 1, 1997.

***Response to Arguments***

4. Claims 1-7 and 10 remain rejected under 35 USC 102(b) as anticipated by Narayanan et al. for the reasons of record in the Official Action mailed 9-12-2000.

Claims 1-7, 19-20, 46-64, 80 and 83 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bennett et al. (US 6,111,094A1), for the reasons of record in the Official Action mailed 9-12-2000.

5. Claim 46 remains rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US Patent No. 6,120,803); Claims 1-7, 10, 12-13, 15, 17-20, and 46-62 remain rejected under 35 U.S.C. 102(e) as being anticipated by McKay et al. (US Patent No. 5,877,309) for the reasons of record set forth in the Official Action mailed 9-12-2000.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JLE  
February 21, 2002

Janet L Epps  
Examiner  
Art Unit 1635

JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
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